

PATENT COOPERATION TREATY

CK

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

RANBAXY LABORATORIES LIMITED
Attn. Deshmukh, Jay R.
600 College Road East
Suite 2100
Princeton, NJ 08540
UNITED STATES OF AMERICA

RECEIVED

JAN 31 2005

RANBAXY
I.P. DEPARTMENT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing
(day/month/year)

27/01/2005

Applicant's or agent's file reference

RLL-437WO

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/IB2004/002957

International filing date
(day/month/year)

13/09/2004

Applicant

RANBAXY LABORATORIES LIMITED

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

Josef Ullrich

MRL ✓



NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference RLL-437WO	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/IB2004/002957	International filing date (day/month/year) 13/09/2004	(Earliest) Priority Date (day/month/year) 12/09/2003
Applicant RANBAXY LABORATORIES LIMITED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box II).

3. ☐ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 1

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

national Application No

PCT/IB2004/002957

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07D305/12 C12P17/02 A61K31/365

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07D C12P A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, WPI Data, BIOSIS, BEILSTEIN Data, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 156 911 A (STEINWENDER ERICH ET AL) 5 December 2000 (2000-12-05) cited in the application	1-10, 13-22
X	column 7, line 59 - column 8, line 17; claims 22,44; examples 1,2 column 10, line 38 - line 40 column 11, line 19 - line 36	11,12, 23,24
A	CAIRA M R: "CRYSTALLINE POLYMORPHISM OF ORGANIC COMPOUNDS" TOPICS IN CURRENT CHEMISTRY, SPRINGER, BERLIN, DE, vol. 198, 1998, pages 163-208, XP001156954 ISSN: 0340-1022 page 166, paragraph 4	1-10, 13-22

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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * & * document member of the same patent family

Date of the actual completion of the international search

19 January 2005

Date of mailing of the international search report

27/01/2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Härtinger, S

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB2004/002957

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 03/047531 A (KERI VILMOS ; CSORVASI ANDREA (HU); BIOGAL GYOGYSZERGYAR (HU); ARONHIM) 12 June 2003 (2003-06-12)	1-10, 13-22
X	page 18, line 25 - line 27; figures 1,2; examples 6-21 page 5, line 1 - page 7, line 11 -----	11,12, 23,24
A	WO 02/098413 A (HOFFMANN LA ROCHE) 12 December 2002 (2002-12-12)	1-10, 13-22
X	page 4, line 10 - line 15; example 8 page 6, line 1 - line 13 -----	11,12, 23,24

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IB2004/002957

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6156911	A	05-12-2000	AT 228118 T	15-12-2002
			CA 2296996 A1	29-07-2000
			CN 1266058 A	13-09-2000
			DE 60000796 D1	02-01-2003
			DE 60000796 T2	18-09-2003
			DK 1028115 T3	17-03-2003
			EP 1028115 A1	16-08-2000
			ES 2185523 T3	01-05-2003
			JP 3445209 B2	08-09-2003
			JP 2001039962 A	13-02-2001
WO 03047531	A	12-06-2003	EP 1458882 A2	22-09-2004
			EP 1470116 A2	27-10-2004
			WO 03048335 A2	12-06-2003
			WO 03047531 A2	12-06-2003
			US 2003149095 A1	07-08-2003
			US 2003138919 A1	24-07-2003
			US 2004162335 A1	19-08-2004
WO 02098413	A	12-12-2002	BR 0210267 A	20-07-2004
			CA 2448035 A1	12-12-2002
			WO 02098413 A2	12-12-2002
			EP 1399153 A2	24-03-2004
			JP 2004532272 T	21-10-2004
			US 2003039686 A1	27-02-2003

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IB2004/002957

International filing date (day/month/year)
13.09.2004

Priority date (day/month/year)
12.09.2003

International Patent Classification (IPC) or both national classification and IPC
C07D305/12, C12P17/02, A61K31/365

Applicant
RANBAXY LABORATORIES LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.



Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2004/002957

19/07/2002
PCT/ISA/237 10 MAR 2005

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2004/002957

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 12,24

because:

- ☒ the said international application, or the said claims Nos. 12,24 with respect to IA relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2004/002957

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ not paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos.

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-10,13-22
	No: Claims	11-12,23-24
Inventive step (IS)	Yes: Claims	1-10,13-22
	No: Claims	11-12,23-24
Industrial applicability (IA)	Yes: Claims	1-11,13-23
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

PCT/IB2004/002957

Re Item III.

Claims 12 and 24 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Art. 34(4)(a)(I) PCT).

Re Item IV.

The separate groups of inventions are:

Group A: subject-matter relating to Form II

Group B: subject-matter relating to Form I

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

On page 1 of the description the applicant acknowledged the prior art existing for crystalline orlistat in Form I and Form II. Hence, none of these crystalline forms can define the "special technical feature" in the sense of Rule 13.2 PCT, because the products as such belong to the prior art. By consequence, each preparation process leading to either Form I or Form II defines a separate contribution over the prior art, whereby the technical features, which define the inventions, reside from the individual process features of either group, i.e. the isolation of orlistat from ether containing solutions (Group A) or from a melt of orlistat (Group B). The technical problem underlying each group is considered to be the provision of an alternative, or possibly improved process for the preparation of a known chemical entity. Since the solution involves distinct technical features, the requirements of unity of invention are not met.

As the search for all groups of inventions could be performed without extra effort, this Authority chose not to invite the applicant to pay further search fees.

Re Item V.

The following documents are referred to in this communication:

D1 : US 6 156 911 A

D2 : CAIRA M R: "CRYSTALLINE POLYMORPHISM OF ORGANIC COMPOUNDS"
TOPICS IN CURRENT CHEMISTRY, SPRINGER, BERLIN, DE, vol. 198, 1998,
pages 163-208, XP001156954 ISSN: 0340-1022

D3 : WO 03/047531 A

D4: WO 02/098413 A

Novelty:

The subject-matter of claims 11 and 23 relates to pharmaceutical compositions, which contain Form I or Form II of orlistat, which has been prepared according to one of the present synthetic methods. Being as such, these claims are considered to be a "product-by-process" claim. In order to be novel, the products per se would have to be novel. This is, however, not the case. As the existence of both forms and their utility to treat obesity and hyperlipaemia has been acknowledged in the description on page 1, the requirements of Art. 33(2) PCT are not met by claims 11 and 23 (see also the cited passages of D1 and D4 in the International search report).

For analogous reasons, the method of treatment claims 12 and 24 lack novelty in the sense of Art. 33(2) PCT.

None of the cited documents disclose the use of one or more ethers in the purification and/or crystallization of orlistat. The subject-matter of claims 1-10 is therefore considered novel in the sense of Art. 33(2) PCT.

None of the cited documents disclose a drying step applied to a melt of orlistat. The subject-matter of claims 13-22 is therefore considered novel in the sense of Art. 33(2) PCT.

Inventive step:

Document D3, which is considered to represent the most relevant state of the art for the group A of inventions, discloses on pages 5 to 7 the use of apolar and polar solvents in the purification of orlistat. No solvent of the class of ethers is, however, disclosed. Hence, the problem underlying the group A of inventions is considered to be the provision of an alternative process for the synthesis of orlistat Form II. The problem has been solved by the use of ethers (see Example 1). The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Art. 33(3) PCT), since a change in the process features may have an unpredictable effect on the nucleation rate in polymorphic products (see D2, page 166).

As the class of ether solvents has so far not been suggested to purify orlistat, the change in process features with regard to the closest prior art is considered to have involved an inventive step.

Document D1, which is considered to represent the most relevant state of the art for the group B of inventions, discloses in columns 7-8 the use of non-polar solvents, preferably hexane and heptane, to crystallize orlistat. No indication may be found in this document, that thermal treatment of the product may alter its crystalline state. Hence, the problem of providing an alternative process for the synthesis of orlistat Form I is considered to be solved (see Example 2) in a not obvious manner. The solution to this problem proposed in claim 13 of the present application is considered as involving an inventive step (Art. 33(3) PCT), since the effect of the newly introduced process feature could not have been predicted.

Re Item VIII.

The last paragraph on page 6 of the description created doubt as to the subject-matter, for which protection is sought. It renders therefore the scope of the claims unclear.

Claims 9 to 10 and claims 21 to 22 relate to the features of the figures 2-3, 4-6. As the IR spectra do not allow a precise determination of the spectral peak frequencies due to the crude scale and missing indications of peak frequencies, figures 2 and 5 cannot define the products in clear and unambiguous terms. Likewise, as the experimental conditions for recording the DSC plots of figures 3 and 6 are not mentioned in the description, the position of the endotherm peak cannot define the products in clear terms (see also Rule 6.2a PCT).